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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,365	06/19/2001	Mark A. Reiley	1759.2570-CIP 4 CON	3566
26308	7590	04/08/2005	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER

3731

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,365

Applicant(s)

REILEY ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8 and 10-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8, and 10-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/04, 1/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2005 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to base claim 26, the "boundary" having an "inner layer" of compacted cancellous bone and an "outer layer" of "noncompacted cancellous bone" is not described in the specification.

Art Unit: 3731

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 7, 8, 10-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (5,108,404) in view of Wang et al. (5,403,340). Scholten et al. disclose the invention substantially as claimed. Scholten et al. disclose, in figures 21-24 and 33 and in col. 7, lines 4-35 and col. 8, line 49 to col. 9, line 17, a method for treating a vertebral body comprising introducing a void creation device (76), an inflatable body, or a balloon into the vertebral body (66) with an interior volume of at least in part, cancellous bone between cortical walls, expanding a region of the void creation device in cancellous bone for forming a void in the interior volume, displacing cortical bone (see col. 7, lines 21-24), and placing a volume of filling material into the void. Scholten et al. also disclose that the region assumes a predetermined shape and size when substantially expanded, where the region includes an anterior-to-posterior dimension

Art Unit: 3731

that is less than the anterior-to-posterior anatomic measurement and/or a side-to-side dimension that is less than the side-to-side anatomic measurement. That is, according to col. 7, lines 26-35, the method of Scholten et al. includes compacting cancellous bone to form a "dam" (of compacted cancellous bone) between the void and the interior cortical walls, such that the dimensions of the expanded region are inherently less than the aforementioned anatomic measurements. However, Scholten et al. do not disclose a void created by the expanded body that is less than the interior volume, where the void volume occupies a percentage of the interior volume as claimed. Scholten et al. do not disclose that the region includes a material that undergoes stress as a result of expansion, such that in a subsequent expansion, the region cannot be relied upon to reach the predetermined shape and size; disposing the void creation device, and instructing against reuse of the plastically deformed body. Scholten et al. also do not disclose vinyl, nylon, polyethylene, an ionomer, polyurethane, polyethylene, and tetraphthalate and expandable body materials. Wang et al. teach, in col. 2, lines 11 to col. 3, line 16 and col. 5, lines 57-62, balloons or expandable bodies comprising materials as claimed, where the bodies can include plastically deformed, "non-compliant" balloons. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wang et al., to apply a plastically deformed or "non-compliant" expandable body, or at least a body having a plastically deformed or "non-compliant" expansion phase, in the method of Scholten et al. Such a body has the hardness and rigidity and shape retention, in its fully-expanded condition, for compacting cancellous bone to a desired bone cavity size and shape. Also, it would be

Art Unit: 3731

a matter of design choice to choose one of the materials as claimed for the region of the void creation device. The choice would be dependent upon the desired amount of compliance (i.e., range of radial expansion) for the vertebral body being treated. It would also be obvious to instruct against reuse of the void creation device and dispose the unsterile device and prevent a possible catastrophic failure of the device and the spread of infection if it were used again. A plastically deformed or "non-compliant" device can only compact cancellous bone to a relatively fixed geometry, and if a larger cavity is desired or if "recoil" of the cancellous bone into the cavity occurs, another expandable body of a larger size, shape, or compliance curve, would be necessitated for the cancellous bone compaction. Also, it would be a matter of design choice to create a void in a vertebral body that has a volume less than the interior volume. The choice of void volume would be dependent upon the size of the vertebral body, the nature of the bone wounds, and the amount of filling material necessary for filling the vertebral body. A void with a volume less than the interior volume could be chosen for a substantially healthy vertebral body requiring only minor filling or repair.

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. in view of Wang et al. as applied to claims 7 and 25 above, and further in view of Levy. Scholten et al. in view of Wang et al. disclose the invention substantially as claimed, but do not disclose a region made of latex or silicone. Levy (4,490,421) teaches, in col. 1, lines 24-39, the use of latex ("thermoplastic rubbers") and silicone ("silicone polycarbonate copolymers") in balloon catheters. It would have been a matter of design choice to apply latex or silicone in the expandable body of Scholten

Art Unit: 3731

et al. in view of Wang et al. The choice would be dependent upon the desired amount of compliance (i.e., range of radial expansion) for the size of vertebral body being treated.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

April 6, 2005